CONFIDENTIAL

510(K) Summary

MAY - 9 2007

Date: May 4, 2007
Submitted by: Lisa Simpson
Regeneration Technologies, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4326 Fax: 386-462-1627

Proprietary Name:
Sterling® IF Screw Eyelet

Common Name:
soft tissue graft fixation device

Product Code:
HWC, Orthopedics Panel

Code Section:
21 CFR 888.3040

Substantial Equivalence:
The Sterling IF Screw Eyelet is substantially equivalent to the LinX HT in design and function, and substantially equivalent to the Sterling Interference Screw ST and Sterling Interference Screw HT in materials and function.

Description:
The Sterling IF Screw Eyelet is manufactured from bovine bone processed with the BioCleanse® Tissue Sterilization Process. The Sterling IF Screw Eyelet is 25mm long by 8mm wide with an oval eyelet. The subject Sterling IF Screw Eyelet devices are to be used with Sterling Interference Screw HT cleared via K060253.

Intended Use:
This device is for use in graft fixation (for example, ligament and tendon), in cruciate ligament reconstruction surgeries. The Sterling IF Screw Eyelet devices are to be used with Sterling Interference Screw HT.

Summary of Technological Characteristics:
The Sterling IF Screw Eyelet, Sterling Interference Screw ST and Sterling Interference Screw HT are composed of the same materials processed in the same manner. The source of bovine bone used in the manufacture of the Sterling IF Screw Eyelet is a closed herd located in the U.S.A. A viral inactivation study using a worst-case representation of the BioCleanse® Tissue Sterilization Process, used in the manufacture of the Sterling IF Screw Eyelet, has shown a reduction of a panel of viruses to below detectable limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Regeneration Technologies, Inc.
% Ms. Lisa Simpson
Director of Regulatory Affairs
11621 Research Circle
Alachua, Florida 32616-2650

MAY - 9 2007

Re: K063584
Trade/Device Name: Sterling® IF Screw Eyelet
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, JDR
Dated: April 20, 2007
Received: April 23, 2007

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melk MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063584

Device Name: Sterling® IF Screw Eyelet

Indications for Use:

This device is for use in graft fixation (for example, ligament and tendon), in cruciate ligament reconstruction surgeries. The Sterling IF Screw Eyelet devices are to be used with Sterling Interference Screw HT.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063584